

# Regulation 61-114

## South Carolina Birth Defects Program

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<b>Statutory Authority:</b>	S.C. Code Sections 44-44-10 through 44-44-160
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## **Section A: Purpose and Scope**

This regulation establishes standards for implementing provisions of Sections 44-44-10 through 44-44-160 of the South Carolina Code of Laws, 1976, as amended, regarding the public health monitoring of birth defects identified in children up to two years of age in South Carolina. The Birth Defects Act of 2004 established the South Carolina Birth Defects Program (SCBDP) within the Department of Health and Environmental Control. The Department has been given the legislative mandate to promulgate regulations for public health monitoring of birth defects and to ensure compliance with the public health monitoring of children born in South Carolina. The responsibilities of the various agencies, institutions and persons involved in public health surveillance and monitoring of birth defects are defined. Procedures for public health surveillance and monitoring, use of data, and maintenance of confidentiality are included.

## **Section B: Definitions**

1. “Birth defect” is defined as a structural malformation, deformation, or disruption, present at birth, as determined before or after birth.
2. “Department” means the South Carolina Department of Health and Environmental Control.
3. “Child” is defined as a child up to two years of age.
4. “Identifying Information” is defined as the child’s legal name, aliases, birth date, time of birth, place of birth, birth weight, race, ethnicity, parent’s or legal guardian’s complete name, complete address and telephone number; mother’s Social Security number and other information as deemed necessary by Department.
5. “ICD-9-CM diagnostic code categories” is the International Classification of Disease which assigns code numbers to each of the birth defects or any subsequent method of classification as may be adopted from time to time.
6. “Active surveillance system” is the process that is used to identify cases and collect data about children with birth defects. An active surveillance system utilizes case abstractors to conduct on-site visits to medical facilities to abstract information directly from medical records and other sources.

## **Section C: Public Health Surveillance and Monitoring of Birth Defects**

1. The Department shall conduct statewide monitoring of all major structural birth defects using active surveillance methods to ascertain cases. This monitoring may be both prenatal and postnatal (up to two years of age) and shall include live births and fetal deaths occurring in South Carolina. South Carolina Birth Defects Program Nurse Abstractors will conduct active surveillance at all hospitals in South Carolina that provide obstetrical or pediatric care for case identification and abstraction. Hospitals and other medical facilities will provide, upon request, access to medical records containing ICD-9-CM diagnostic code categories in the range of birth defects codes recommended by the Centers for Disease Control (CDC) and the National Birth Defects Prevention Network (NBDPN) for surveillance. The categories of ICD-9-CM codes for birth defects includes, but is not limited to, the following:

- a. Central nervous system disorders
- b. Eye and ear disorders
- c. Cardiovascular disorders

- d. Orofacial disorders
- e. Gastrointestinal disorders
- f. Genitourinary disorders
- g. Musculoskeletal disorders
- h. Chromosomal disorders
- i. Other disorders to include Fetal Alcohol Syndrome and Amniotic bands
- j. ICD-9-CM codes regarding known or suspected fetal abnormality affecting management of mother.

2. The birth defects surveillance system will be implemented by phasing in additional birth defect categories until all CDC recommended types of birth defects are monitored.

3. Birth defects case abstraction information will include demographic data on the child, mother and father, if available.

4. The Department shall maintain a central database of all birth defects data gathered from hospitals, specialty clinics and other facilities, regarding births, pregnancies, stillbirths, and pediatric deaths through age two, throughout the state, including border regions.

5. The Department may enter into agreements with other states, health care facilities, and other entities in order to conduct monitoring of birth defects.

#### 6. Monitoring

a. Upon request, the Department shall have access to all records of parent(s), child, and siblings if necessary, for the purpose of identifying birth defects, including vital records, hospital medical records, physician office medical records, specialty clinic records, and discharge data, in order to identify birth defect cases. The Department shall verify the cases through records review and may include review by a physician geneticist.

b. For the purpose of surveillance and identification of birth defects, all laboratories, universities, and other sources of birth defects information shall provide the Department access to all health, medical, or other records, upon request.

c. Access to all records described herein may be granted in hard copy or electronically.

### **Section D: Data Usage**

1. Unless otherwise provided by law, all reports generated by the Department containing birth defects data will be publicly disclosed in aggregate form only. No identifying information will be publicly released by the Department.

2. Birth defect data may be used by the Department, its agents, partners and contractors, to facilitate optimal treatment services for affected children and families.

3. Any entity or person wishing to conduct research using this data must comply with the Department's procedures, including review by the Institutional Review Board (IRB).

4. The Department may negotiate and enter into agreements and contracts with state and federal agencies, other states, universities, genetic centers and other parties, as appropriate, in order to facilitate operation of the program. These agreements and contracts may include the release of identifying data to enable the other entity to offer families assistance for prevention of recurrence of birth defects.

### **Section E: Referral**

1. The Department may contact a family whose child is identified as having a structural birth defect either directly or through the child's health care provider in order to offer services. Family acceptance of referrals is voluntary. Referrals shall be made in accordance with the Department guidelines and recommendations.

2. South Carolina Birth Defects Program nurse abstractors will conduct surveillance activities, to include review of medical records for documentation of physician, social work or discharge planner referral for follow-up of children with birth defects. When there is no documented evidence of follow-up, South Carolina Birth Defects Program staff may access other appropriate health and developmental systems or organizations for referral for early intervention, such as Babynet. Babynet will provide regular feedback, as requested, to South Carolina Birth Defects Program on status of birth defects cases referred.

### **Section F: Confidentiality**

These records will be kept confidential and used and released pursuant to the provisions of S.C. Code Ann. Section 44-44-140 only.

### **Section G: Severability**

In the event that any portion of this regulation is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of this regulation, and they shall remain in effect as if such invalid portions were not originally a part of these regulations.